

**REMARKS**

Claims 1-7, 11-14, and 16-21 are currently pending in this application, with claims 1-7 having been withdrawn from consideration in response to a previous restriction requirement. Claim 11 is in independent form.

**Information Disclosure Statement**

The Examiner has indicated that five references identified on an Information Disclosure Statement were not considered because the references were not provided in the English language. Applicants submit herewith a Supplemental Information Disclosure Statement identifying these references accompanied by an English-language counterpart or an English-language abstract. The Examiner's consideration of these references is requested.

**Rejections Pursuant to 35 U.S.C. § 112, second paragraph**

The Examiner has rejected claims 11-14 and 16-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, claim 11 has been identified as being indefinite as it is not clear whether each of the two layers of the first membrane has at least two layers (for a total of at least four layers), or whether the first membrane simply has two layers. Applicants have amended claim 11 to delete the phrase "at least two layers having" and now recites, in relevant part, "wherein the first membrane has a biodegradable layer and an adhesion preventive layer".

Claim 12 has also been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for insufficient antecedent basis for the term "the tissue". Applicants have amended claim 12 to recite, in relevant part, "wherein the injured or deficient tissue".

Applicants submit that in view of the amendments to claims 11 and 12, claims 11-14 and 16-21 are definite. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, are respectfully requested.

Application No. 10/594,801  
Paper Dated: June 26, 2009  
In Reply to USPTO Correspondence of January 29, 2009  
Attorney Docket No. 3274-062407

Rejections Pursuant to 35 U.S.C. § 103(a)

Claims 11-14 and 16-21 have been rejected under 35 U.S.C. § 103(a) as being obvious over United States Patent Publication No. 2003/0114061 to Matsuda (“Matsuda”) in view of United States Patent Publication No. 2004/0115241 to Calhoun (“Calhoun”). The Office Action alleges that Matsuda discloses adhesion preventative membranes comprised of a first membrane made of a collagen nonwoven fabric layer that provides membrane strength. The Office Action further contends that the biodegradable base layer may be laminated with a coating layer, containing a mixture of collagen and hyaluronic acid that prevents adhesion. However, the Office Action acknowledges that Matsuda fails to disclose sandwiching an injured tissue by two membranes or by a tissue-sandwiching portion of one membrane. To rectify this deficiency, the Office Action applies Calhoun as disclosing anti-adhesion membranes for use with implants to prevent post-surgical adhesions between the implant and the surrounding tissue. Calhoun discloses a method of reducing adhesions resulting from a surgical implant by covering all surfaces of an implant with a bioresorbable anti-adhesion membrane.

According to the Office Action, it would have been obvious to combine the membranes of Matsuda with the covering of an implant as disclosed in Calhoun. As recited on page 6 of the Office Action “[o]ne would have been motivated to do so since Matsuda does not disclose specific methods for the use of the disclosed membranes, but rather teaches that the inventive membranes can be used in known manners and in accordance with known methods.” The Office Action further contends that “[w]hile it is well within the skill of the ordinary artisan to determine the optimal placement of adhesion preventing membranes at the sites at which adhesion prevention is desired, the artisan would be motivated to look to the literature for guidance in the absence of specific teachings by Matsuda.”

As a preliminary matter, although Matsuda discloses an adhesion preventive membrane formed by laminating a nonwoven fabric layer made of collagen fibers, and a coating layer containing a mixture of collagen and hyaluronic acid (*see* paragraph [0091]), Matsuda does not disclose applying two membranes on opposing sides of a tissue. In addition, Calhoun discloses shrink-wrapping, spray coating, or dipping an implant with an anti-adhesion coating. However, Calhoun does not disclose applying two membranes on opposing sides of a tissue.

Accordingly, neither Matsuda, nor Calhoun, nor the combination of Matsuda and Calhoun disclose or suggest sandwiching an injured tissue with a first and second membrane.

It appears that the Examiner has mischaracterized the teachings of both Matsuda and Calhoun, as these references represent the conventional methodology as shown in Fig. 5 (prior art) of the present application. As described in paragraph [0007] of the present application, the conventional adhesion preventive membrane (such as described in Matsuda and Calhoun) allows for the edges of the injured tissue to adhere to the surrounding tissue, as shown in Fig. 5. In contrast, the presently amended claim 11 recites, in relevant part:

sandwiching an injured or deficient portion of the injured or deficient tissue by (A) a first membrane and a second membrane or by (B) a tissue sandwiching part of an adhesion preventive membrane, so that the injured or deficient portion is not exposed and the portion is not in physical contact with the surrounding tissue...

Neither Matsuda nor Calhoun disclose applying a second membrane having an adhesion prevention layer to the opposite side of the injured tissue. Accordingly, even if Matsuda and Calhoun were combined, the resulting combination would not disclose all of the claimed limitations, *i.e.*, sandwiching an injured tissue between a first membrane and a second membrane.

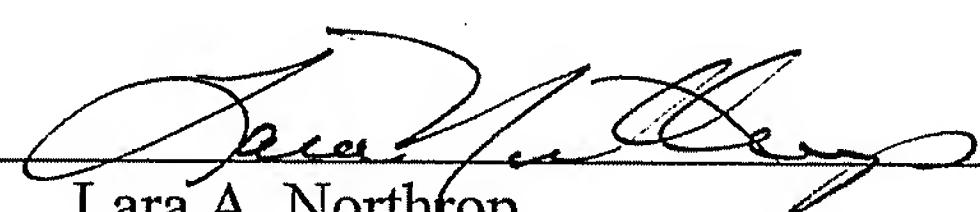
Moreover, there is no motivation or reason to apply a second membrane in either Matsuda or Calhoun. The Office Action asserts that “[w]hile it is well within the skill of the ordinary artisan to determine the optimal placement of adhesion preventing membranes at the sites at which adhesion prevention is desired, the artisan would be motivated to look to the literature for guidance in the absence of specific teachings by Matsuda.” However, this is a conclusory statement, and does not satisfy the requisite motivation to combine or alter the references. See MPEP § 2141, citing *In re Hahn*, 441 F3d 977, 988 (Fed Cir. 200(1)). Rejections based on “obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1395 (2007).

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Applicants respectfully request that this rejection be reconsidered because 1) neither Matsuda, nor Calhoun, nor the combination of Matsuda and Calhoun disclose or suggest sandwiching a tissue between a first and second membrane, and 2) a reason to combine the references has not been provided.

Applicants respectfully traverse the rejection of claims 11-14 and 16-21 under 35 U.S.C. § 103(a). Applicants submit that claims 12-14 and 16-21 depend directly from independent claim 11 and are believed patentable for at least the reasons discussed above. Reconsideration of the rejections and allowance of pending claims 11-14 and 16-21 are respectfully requested.

Respectfully submitted,  
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